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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/549,036	04/13/00	FARRELL G	MST-2322.1

IM52/1108

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EXAMINER	
HANDY, D	
ART UNIT	PAPER NUMBER
1743	4

DATE MAILED: 11/08/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/549,036	Farrell
Examiner	**Art Unit**
Dwayne K. Handy	1743

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Apr 13, 2000*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *18-22* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *18-22* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 18-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 18, applicant recites the limitations of a "sample volumetric delivery rate" and a "sheath volumetric delivery rate". It is the Examiner's contention that these phrases are unclear. What are the actual (numerical) flow rates? For example, are these fluids - both sample and sheath fluids - delievered at a rate which occurs when the system is started or finished operating? These flow rate values are further clouded by the fact that applicant's method later recites varying both flow rates in response to control parameters. If the beginning values of these flow rates are unclear, then the Examiner fails to see how one could know exactly what value to allow the fluids to flow at to provide the proper flow rate in response to control parameters. Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bezanson (Pat. No. 5,106,187) in view of Sklar et al. (5,895,764). Bezanson teaches a method and an apparatus for particle identification. Bezanson's teachings disclose every element of applicant's method except for teaching a sheath fluid which is delivered in laminar flow. Bezanson recites delivering sample and sheath fluid streams (col. 2, lines 11-23), drawing the sample into a suspension stream of fixed diameter (col. 2, lines 13-14), and detecting a characteristic of the sample (col. 2, lines 38-42). Bezanson later recites use of computer to analyze signals and compare the signals to preset limits. The results from the analysis are then used to control the operation of the valves and pumps within the system (Figure 3, also col. 3, lines 37-65). As to the limitations of claims 19 and 20, Bezanson discloses detection of particles and particle

mixtures in the abstract and invention summary and in claim 2. Finally, Bezanson teaches controlling the pumping rates for optimal characteristic detection (waveform resolution) in column 3, lines 24-28. Sklar et al. discloses a method for controlled sheath flow cytometry. Their method also includes delivering the sample in a suspension stream which includes a sheath flow. Furthermore, the sheath flow is controlled to yield stable laminar flow (col. 3, lines 25-27 and 60-67). Sklar then teaches why they control the sheath flow to yield a laminar flow stream at the top of column 4. Sklar states "When the normal laminar flow is perturbed, some beads will not flow through the optimal laser focus point and will be measured with a reduced fluorescence". It would have been obvious to one of ordinary skill in the art then, to combine the teaching of the use of a laminar sheath flow when using a flow cell in order to insure an accurate reading of the particles flowing through the cell. Both Sklar et al. And Bezanson use flow cells to analyze the particles which are present in the sample. The use of laminar sheath flow would yield better results when combined with the method of Bezanson.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Yamamoto also teaches a method of flow cytometry using a system of sheath and sample pumps and a flow cell which are operated under computer control. Toge, Hirschfeld, Kurimura et al., and Imai et al. all teach particle analyzing systems and/or methods of analysis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K. Handy whose telephone number is (703)-305-0211. The examiner can normally be reached on Monday-Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703)-308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703)-772-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0661.

JEFFREY SNAY
PRIMARY EXAMINER

dkh

November 7, 2001